IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	:	**Master Docket: Misc. No. 21-mc-1230-JFC**
	:	**MDL No. 3014**
This Document Relates to:	:	
Consolidated Second Amended Class Action Complaint for Medical Monitoring (ECF No. 815)	:	
and	:	
Amended Master Long Form Complaint for Personal Injuries and Damages, and Demand for Jury Trial (ECF No. 834)	:	

REPLY MEMORANDUM OF DEFENDANTS POLYMER TECHNOLOGIES INC. AND POLYMER MOLDED PRODUCTS, LLC IN FURTHER SUPPORT OF MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(2) AND 12(b)(6)

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PRELIMINARY STATEMENT

PolyTech's arguments are straight forward premised around the fact that PolyTech manufactures a foam product in Delaware and Massachusetts, there are no allegations the foam was defective, and no facts alleged supporting Plaintiff's claims that PolyTech was involved in the design, manufacture, or marketing of the Recalled Devices. Plaintiff attempts to manufacture a conspiracy that PolyTech was involved in concealing a dangerous condition by responding to two e-mails in 2015 and 2018 in which Philips reached out regarding a condition that was brought to its attention by a customer about foam degrading. From that, Plaintiff has asserted bare boned claims of negligence, design defect, failure to warn, and manufacturing defect without pleading facts that PolyTech did anything more than manufacture a foam product. [1]

As stated, the entire premise for Plaintiff's Complaints against PolyTech[2] are two e-mail strings from 2015 and 2018 in which employees of Philips reached out to PolyTech inquiring about a single "message from a customer that the foam was degrading over time" in 2015 and about an issue with the foam, that they "are moving forward with a preventive maintenance plan wherein the foam would be replaced every few years", and to "evaluate other materials that can be used in the air path of our respiratory devices…" in 2018.[3] In addition to providing information sought by Philips, Bob Marsh with PolyTech responded with a proposed solution

[1] PI Complaint at Counts I, II, III, IV, V, VIII, and IX; MM Complaint at Claims First, Fourth, Fifth, Sixth, Seventh, Eighth, and Fourteenth.
[2] Polymer Technologies, Inc. and Polmer Molded Products, LLC are referred to as "PolyTech".
[3] PI Complaint ¶ 195-199, 208-219 and exhibits 94, 95; MM Complaint ¶ 260, 271-281 and exhibits 98, 100. The 2015 and 2018 e-mails are attached to Plaintiff's Complaint at Exhibit 95 but are attached hereto as Exhibits "A" and "B" for ease of reference.

that the "best material we have for chemical/environmental compatibility is our melamine foam" and provided literature from the material manufacturer.

As pled, Plaintiff's claims against PolyTech are speculative at best, not plausible, and do not rise to the level sufficient under *Twombly* and *Iqbal*. In *Plaintiffs' Combined Brief in Opposition to The Non-Philips RS Defendants' Motions to Dismiss the Second Amended Medical Monitoring Complaint and Amended Personal Injury Complaint for Failure to State a Claim* ("Opposition to Non-RS MTD"); *Plaintiffs' Brief in Opposition to Philips RS North America LLC's Motion to Dismiss Plaintiffs' Consolidated Second Amended Class Action Complaint for Medical Monitoring for Failure to State a Claim Pursuant to Fed. R. Civ. P. 12(b)(6)* ("Opposition to RS MTD MM Complaint"), and *Plaintiffs' Brief in Opposition to Philips RS North America LLC's Motion to Dismiss Plaintiffs' Amended Master Long Form Complaint for Personal Injuries and Damages for Failure to State a Claim Pursuant to Fed,. R. Civ. P. 12(b)(6)* ("Opposition to RS MTD PI Complaint"), Plaintiff meticulously set forth copious facts supporting the control Philips exerted over design and manufacturing of the Recalled Devices.[4] There are no facts asserted that any entity other than Philips[5] designed, manufactured, marketed, or sold the Recalled Devices. Taking these facts in the light most favorable to Plaintiff, as is required by the Court when evaluating a motion to dismiss, Philips exercised exclusive control over design, manufacturing, and marketing of the Recalled Devices.[6] In addition, Philips: designed, manufactured, marketed, and sold CPAP, BiPAP, and ventilator devices[7]; used PE-

[4] *See* Opposition to Non-RS MTD at pages 3-14; Opposition to RS MTD PI Complaint at pages 1-5; Opposition to RS MTD PI Complaint 1-5.
[5] Plaintiff collectively refers to the various entities as Philips which Philips disputes as being accurate and appropriate. PolyTech is not taking a position on whether that is factually appropriate and is simply utilizing this collective designation for ease of reference.
[6] Opposition to Non-RS MTD at pages 3-14.
[7] Opposition to RS MTD PI Complaint at 2.

PUR foam in the devices even though it was widely known that this foam is susceptible to hydrolysis[8]; brought the Devices to market through the 510(k) clearance process[9]; directly oversaw and managed the recall[10]; instituted a repair and remediation program[11]; set up a polyester polyurethane sound abatement foam test and research program[12]; and dealt with US regulatory authorities and Department of Justice[13]. There are no arguments made in those Oppositions that anyone other than Philips was involved in the design, manufacture, market or selling of the Recalled Devices.

In addition to the Oppositions filed by Plaintiff to the Philips RS and Non-Philips RS Motions to Dismiss not alleging or asserting any involvement, collaboration, collusive relationship between Philips and PolyTech, the PI and MM Complaints also do not. Voluminous documents attached are attached to the Medical Monitoring ("MM") and Personal Injury ("PI") Complaints none of which contain facts supporting involvement by PolyTech in the manufacture or design of the CPAP machines. In fact, the Complaints are rife with factual assertions that Philips designed and manufactured the Recalled Devices. Plaintiff argues to the contrary but fails to cite to a single fact that PolyTech designed, manufactured, marketed, or sold the Recalled Devices. The facts asserted are: PolyTech obtained foam from Burnett or another foam supplier and applied an adhesive backing and acoustical lining to the foam "which was provided to Philips for integration in the Recalled Devices"[14] either directly by PolyTech or through an

[8] *Id*. at 3.
[9] *Id*. at 3.
[10] Reply at 11.
[11] *Id*.
[12] *Id*.
[13] *Id*. at 12.
[14] PI Complaint at 70

intermediary.[15] The Complaint asserts the foam was manufactured by Burnett in sheets that are approximately four to six feet wide and one hundred to two hundred feet long[16]; Burnett sold the bulk foam to intermediaries, including PolyTech and Soundcoat[17]; and intermediaries then sold the foam to Philips either directly or through intermediaries such as Paramount Die[18]. The Complaint then cites, and attaches, two e-mails strings that involved representatives from Philips, PolyTech, Paramount Die, and Burnett dated in 2015 and 2018 wherein Philips is seeking information as a result of a single complaint it received from a customer.[19] PolyTech corresponds with Burnett, provides the information sought by Philips, and provides a possible solution.[20] Plaintiff then goes on to cite to numerous findings made by the FDA during its investigation. All of the claims against PolyTech stem from these e-mail exchanges which the U.S. Food and Drug Administration was in possession of when conducting its investigation and issuing its findings.[21]

ARGUMENT

I. Plaintiff Fails to Assert the Court has Specific Jurisdiction over PolyTech Defendants.

In *Travers v. FedEx Corp.*, specific jurisdiction is described as a way to "cover defendants less intimately connected with a State, but only as to a narrower class of claims."[22] As Plaintiff discusses, the "minimum contacts" test is applied to determine whether specific jurisdiction is met. First, there must be a determination of whether the defendant purposefully availed itself of the

[15] PI Complaint at 195-196.
[16] PI Complaint at 195.
[17] PI Complaint at 196
[18] PI Complaint at 196.
[19] Exhibit 95 to PI Complaint and attached hereto as Exhibits "A" and "B".
[20] *Id*.
[21] PI Complaint at 197.
[22] *Travers v. FedEx Corp.*, 584 F. Supp. 3d 1, 5 (E.D. Pa. 2021).

forum state—in this case, Pennsylvania.[23] Second, there must be a determination of whether the Plaintiff's claim(s) arise out of or relate to at least one of those activities.[24] Lastly, there must be assurance that asserting specific jurisdiction comports with the notions of fair play and substantial justice.[25]

1. Plaintiff Fails to Allege PolyTech Purposefully Directed its Activities Towards Pennsylvania.

Plaintiff alleges that PolyTech's engagement in solicitation with potential customers in Pennsylvania and communication with Philips RS's Pennsylvania based-employees satisfies the requirements for specific jurisdiction. However, as previously noted, the acts of PolyTech must be of such a purposeful availment to the privilege of conducting activities within the forum state so as to invoke the benefits and protections of the laws of the state.

Purposeful availment requires the defendant to "exploit the market" in the forum State or enter a contractual relationship centered there.[26] There must be some act "by which the defendant avails itself of the privilege of conducting activities within the forum State."[27] However, these contacts with the forum state cannot be "random, fortuitous, or attenuated."[28] Here, PolyTech simply distributed and discussed the PE-PUR foam product with both potential and current customers. PolyTech did not manufacture or create the PE-PUR foam, and there was no "exploitation" of the market within Pennsylvania. Instead, PolyTech simply acted as an intermediary regarding the distribution of the PE-PUR foam from its supplier to customers. The act of communication and distribution of the PE-PUR foam does not avail PolyTech to the

[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] *Ford Motor Company v. Montana Eighth Judicial District*, 592 U.S. 1017, 1025 (2021).
[27] *Id*.
[28] *Kubik v. Letteri*, 614 A.2d 1110, 1114 (Pa. 1992).

privilege of conducting any activities within the state, nor rise to the level of engaging in business activities with any forum residents.

In contrast to *Ford Motor Company v. Montana Eighth Judicial District*, where Ford was found to have purposefully availed itself to the forum state as Ford had "advertised, sold, and serviced cars in the forum state(s) for many years,[29] PolyTech has not acted in the same or similar manner to satisfy purposeful availment. In *Ford*, the motor company was found to have engaged in countless advertisements to the forum states of both Minnesota and Montana through billboards, TV and radio, and various advertisements.[30] Ford further fostered connections within the state by maintaining and repairing Ford cars. The plaintiffs in Ford suffered injury due to defective products—Ford vehicles—that were extensively promoted, sold, and serviced in the forum states. As such, specific jurisdiction was found via the relationship between the defendant, the forum, and the litigation.[31]

PolyTech did not engage in the level of action as occurred in *Ford* to have purposefully availed itself to Pennsylvania law. While there was correspondence about the foam with prospective and current customers, there was no property owned in Pennsylvania, nor any TV, radio, or print advertisements sent to Pennsylvania attempting to sell the PE-PUR foam. Here, PolyTech engaged in conversations with customers about the PE-PUR foam and responded to various questions about the foam itself.

The present case can be further contrasted from *EQT Prod. Co. v. Aspen Flow Control, LLC*,[32] where a valve supplier was found to have "purposefully availed" itself to the forum state

[29] *Id*. at 1028.
[30] *Id*.
[31] *Id*. at 1032.
[32] *EQT Prod. Co. v. Aspen Flow Control, LLC*, 20 WL 6545997 at *1 (W.D. Pa. Nov. 6, 2020).

based off repeated travels to Pennsylvania to discuss and sell custom designed valves for use in Pennsylvania. In comparison, PolyTech merely discussed PE-PUR foam with customers and distributed the PE-PUR foam in its original state. At no point in time did PolyTech manufacture the PE-PUR foam nor make any custom alterations to the foam. PolyTech did nothing more than distribute the foam and was not engaged in any other processes of creation of the foam. As such, PolyTech was merely a manufacturer that placed the foam product into the stream of commerce which was then placed into the CPAP, BiPAP, and ventilators ("Recalled Devices") at issue. Such actions do not rise to the necessary level of purposeful availment required to satisfy specific jurisdiction.

2. Plaintiff's Claims Do Not Arise Out of and Relate to PolyTech's Pennsylvania Activities.

Specific jurisdiction over a defendant exists "when the defendant has purposefully directed their activities at residents of the forum and the litigation results from alleged injuries that arise out of or relate to those activities."[33] It is further noted that there must be a due process limitation on the degree of permissible attenuation between "the defendant, the forum, and the litigation."[34]

It is important to highlight that potential defendants should have some control over the jurisdictional consequences of their actions. As noted in *RAR, Inc v. Turner Diesel, Ltd.*, "when conducting business with a forum in one context, potential defendants should not have to wonder whether some aggregation of other past and future forum contacts will render them liable to suit there."[35]

[33] *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 95 (3d Cir. 2004).
[34] *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977).
[35] *RAR Inc. v. Turner Diesel, Ltd.*, 107 F.3d 1272, 1278 (7th Cir. 1997).

Here, Plaintiff alleges that PolyTech's involvement of shipping of the PE-PUR foam to Pennsylvania and communicating with Philips RS about the foam demonstrates a relationship directed towards Pennsylvania and is related to the Plaintiff's claims. However, as previously noted, PolyTech held no involvement in the creation or manufacturing of the PE-PUR foam and acted only as a distributor of the foam. Further, PolyTech held no involvement in the research, design, or development of the Recalled Devices, nor took any part in selling the Devices. PolyTech's sole engagement was the distribution of PE-PUR foam for integration into the Recalled Devices. It has further been acknowledged that PolyTech was not the sole distributor of this foam to various customers.

As such, Plaintiff's fail to establish that their claims arise out of and relate to PolyTech's Pennsylvania activities. PolyTech merely engaged in the distribution of foam and should not be held accountable to Plaintiff for the unanticipated aggregation of this contact, as noted in *RAR Inc.,* that has now rendered them liable to suit in Pennsylvania. The only other actions PolyTech engaged in within the state of Pennsylvania were forwarding of e-mail correspondence involving questions regarding the foam to and from a customer to a supplier. Plaintiff attempts to use this information to strengthen their argument. However, these communications between Philips and PolyTech include nothing more than Philips e-mailing PolyTech questions about foam, which PolyTech forwards to their foam supplier, Burnett. Burnett subsequently responded with answers to these questions, which PolyTech forwarded back to Philips. Plaintiff attempts to rely on these communications as a factual basis for the allegations and claims against PolyTech regarding their involvement and "direct relationship" in Pennsylvania activities. However, without more, PolyTech's business activities of distributing foam and corresponding to e-mails does not justifiably permit PolyTech to be rendered liable to suit in Pennsylvania.

3. The Court's Exercise of Jurisdiction over the PolyTech Defendants Fails to Abide by Traditional Notices of Fair Play and Substantial Justice.

If minimum contacts in a forum state have been established, there must be a determination of whether the contacts "are such as to make it reasonable and fair to require the defendant to conduct their defense in the state."[36] There must be a substantial connection with the forum state.[37]

Because such minimum contacts within the forum state of Pennsylvania have not been properly established in this case, it would be both unreasonable and unfair to require PolyTech to conduct their defense in Pennsylvania. Plaintiff's claims are too attenuated and fail to arise out of PolyTech's activities with Pennsylvania. As such, requiring PolyTech to litigate in Pennsylvania would offend traditional notions of fair play and substantial justice.[38] PolyTech's engagement with Pennsylvania involved the distribution of foam and communication between various customers and suppliers. These acts fail to make PolyTech "at home" in the forum state and do not rise to a level of which PolyTech should have anticipated being haled into court in Pennsylvania.

II. The Court Does Not Have Pendent Personal Jurisdiction over all of Plaintiffs' Claims Against the PolyTech Defendants.

It has been consistently recognized that pendent jurisdiction is a doctrine of discretion, not plaintiff's right.[39] The justification for recognizing pendent jurisdiction lies in "considerations of judicial economy, and convenience and fairness to litigants."[40]

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[36] *Mendel v Williams*, 53 A.3d 810, 822 Pa. Super. Ct. (2012).
[37] *Walden v. Fiore*, 571 US 277 (2013).
[38] *Id*.
[39] *Reed v. Philadelphia Housing Authority*, 372 F. Supp 686, 695 E.D. Pa. 1974.
[40] *Id*.

Plaintiff argues that because this Court has jurisdiction over PolyTech for Plaintiffs' RICO statute in the Economic Loss Complaint, the Court can also exercise supplemental jurisdiction over Plaintiff's state law claims as the state law claims form part of the same case or controversy. However, Plaintiffs' RICO claim and state law claims do not form part of the same case or controversy and instead satisfy a basis for the requirement of independent jurisdiction. If the combining of a federal and state claim could cause confusion for a jury when handling different theories or relief, jurisdiction should be refused.[41]

If this Court grants supplemental jurisdiction to Plaintiff's state law claims based off Plaintiff's RICO claim, there will certainly be confusion regarding the issues of the case and remedies for the varying claims. Plaintiff's RICO claim alleges that Polytech and the Philips Defendants conducted or participated in affairs of an "association-in-fact" through a pattern of racketeering activity in violation of the RICO statute. The RICO claim does not relate to Plaintiff's alleged state law claims and instead would cause unnecessary confusion to a jury that would be required to separate the RICO claims, statutes, and theories from the state law claims. These claims do not form part of the same case or controversy. Instead, the RICO claim relies on a federal racketeering statute which is wholly different than the state law claims asserted by Plaintiffs. Allowing the combining of these claims will result in confusion of the underlying legal theories and lead to improper outcomes that will prejudice PolyTech.

III. As Pled, Plaintiff's claims are barred by the Component Parts Doctrine.

Plaintiff argues the Component Part Doctrine does not bar the claims against PolyTech because PolyTech substantially participated in the integration of its product into the end-product. However, Plaintiff has not pled facts sufficient to raise a right to relief above the speculative

[41] *Id*. at 695.

level. Specifically, Plaintiff cites to paragraphs 259-261 and 270 of the MM Complaint and paragraphs 70, 197-199, and 208 of the PI Complaint. These paragraphs do not set forth facts supporting a plausible inference PolyTech had any involvement or participation in the integration of its product into the end-product. The "factual allegations must be enough to raise a right to relief above the speculative level"[42], must be plausible[43], and, taken in the light most favorable to Plaintiff, the paragraphs cited by Plaintiff support that PolyTech manufactured, treated, and processed PE-PUR foam by applying an adhesive backing and an acoustical lining to the foam. It also supports that PolyTech obtained foam from Burnet and that PolyTech and SoundCoat sold foam to Philips or to an intermediary, such as Paramount Die, who modified the foam and sold it to Philips. The facts do not create a plausible inference that PolyTech was involved or participated in the integration of its product into the end-product. In addition, the 2015 and 2018 e-mail correspondences do not plausibly support an inference that PolyTech was involved or participated in the integration of its product into the end-product. In further support of this, Plaintiff specifically asserts that Philips "made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices."[44] Therefore, Plaintiff has failed to plead sufficient facts to plausibly support an inference that PolyTech did anything other than supply a component part that was integrated into an end-product by a third-party.

Plaintiff also argues that dismissal should not be granted where a supplier knows that their component will be used in a dangerous way in the end-product. In support of this, Plaintiff relies on *Suchomajcz*.[45] In *Suchomajcz*, a federal injunction had been entered against a

[42] *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007).
[43] *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).
[44] PI Complaint at paragraph 91.
[45] *Suchomajcz v. Hummel Chemical Co.*, 524 F.2d 19 (3d Cir. 1975).

manufacturer of fireworks and the chemical manufacturer sold its products to the manufacturer of fireworks in violation of the injunction which the chemical manufacturer knew about.[46] The Third Circuit Court of Appeals found the risk in selling of chemicals, knowing its intended and illegal use, was considerable since there was significant possibility that the firecracker assembly kits would cause serious bodily harm.[47] There is no allegation the foam was defective and there are no facts alleged that PolyTech had any involvement in the decision to use PE-PUR foam in the Recalled Devices. In addition, there is no allegation that PolyTech knew or should have known the foam would be used in a manner that would make its safe product dangerous. The court in *Suchomajcz* found "the chemicals in the assembly kit were potentially dangerous precisely because of the probability that the chemicals would be misused."[48] PE-PUR foam is used in many ways by many companies and there are no facts alleged that support PolyTech knew or should have known its product would be used in a manner that would cause harm.

Lastly, Plaintiff argues that some courts have not recognized the component part doctrine, citing specifically to cases from Arizona, Florida, Indiana, and Maine and that the component part defense is more appropriately addressed in a motion for summary judgment following closure of discovery. Setting aside that courts in Illinois, Indiana and Maine have recognized the component part doctrine[49], this does not relieve Plaintiff of the burden under *Twombly* and *Iqbal*

[46] 524 F.2d at 22, 24 (It was pled in the complaint that the chemical manufacturer knew or should have known the chemicals were for use in the sale of firecracker assembly kits in violation of the federal injunctions.).
[47] *Id*.
[48] 524 F.2d at 28.
[49] *Depre v. Power Climber*, 635 N.E. 2d 542 (Ill. App. Ct. 1994); *Rotzoll*, 681 N.E. 2d 156 (Ill. App. Ct. 1997); *TRW Vehicle Safety Systems, Inc.*, 936 NE. 2d 201 (Ind. 2010); *Thorndike*, 2003 WL 21212591 (D. Me. May 21, 2003).

that some factual basis for the claim that PolyTech was involved or participated in the design of the end-product must be pled creating a plausible claim for relief which Plaintiff has not.

IV. As Pled, Plaintiff's claims are insufficient and speculative under *Twombly* and *Iqbal* and should be dismissed.

Plaintiff argues that the Complaint provides PolyTech with more than enough information about the products at issue, the timeframe in which the products were produced, and when and how Plaintiff was injured by the products and that is all that is required. The claims against PolyTech are not that its product caused harm. The allegation is that how PE-PUR foam was used in the Recalled Devices caused harm with claims against PolyTech for negligence design defect and manufacturing defect. These claims are all regarding the Recalled Devices, not the foam. Again, there is no claim the foam is dangerous. Moreover, Plaintiff has not pled any facts that plausibly support PolyTech was involved in the design, manufacture, sale, or had any other involvement beyond: (1) supplying foam to either Philips or an intermediary such as Paramount Die who did something to the foam and then supplied it to Philips and (2) responding to inquiries from Philips regarding an issue a customer raised about foam degradation, including providing a possible solution to the issue. Facts are not pled that raise the right to relief above the speculative level.

CONCLUSION

WHEREFORE Defendants Polymer Technologies, Inc. and Polymer Molded Products, LLC respectfully respect that the foregoing Motion be GRANTED, Plaintiff's Complaint be dismissed, and for such other relief as this Honorable Court finds appropriate and as justice requires.

Respectfully Submitted,

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